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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
013341-000020

Application Number	Filed
10/065,279	September 30, 2002
First Named Inventor	
Jeffrey C. Leung	
Art Unit	Examiner
3731	Tuan Van Nguyen

Applicant requests review of the final rejection in the above-identified application.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

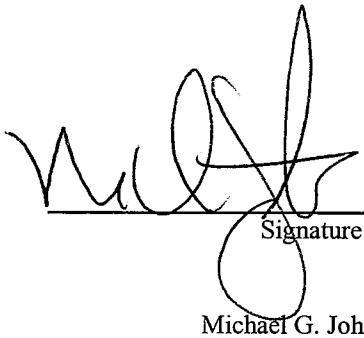
☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.7.1. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 38,194.

☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34_____



Signature

Michael G. Johnston
Typed or printed name

919-286-8000
Telephone number

March 4, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed applicable form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:	)		
	)	**Docket No:**	**013341-000020**
Applicants: **Leung, et al.**	)		
	)	**Examiner:**	**Tuan Van Nguyen**
Application No.: **10/065,279**	)		
	)	**Art Unit:**	**3731**
Filed: **September 30, 2002**	)		
	)	**Confirm. No.:**	**5693**
Title: **Barb Configurations for Barbed Sutures**	)		
	)	**Customer No.:**	**24239**
	)		

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REMARKS IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR REVIEW

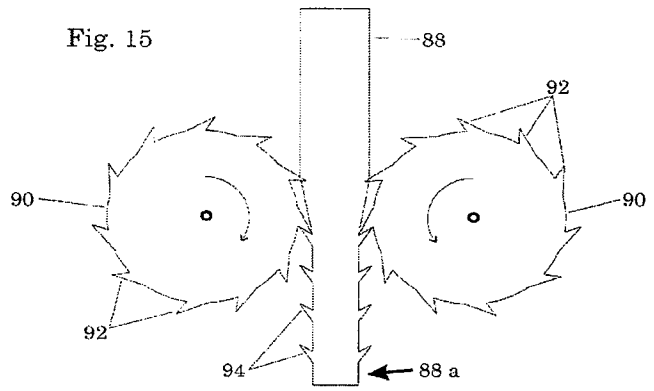
Applicants submit that the current and preceding office actions issued by the Examiner in the present application contain clear errors in the Examiner's rejections as well as omissions of one or more essential elements needed for a *prima facie* rejection under 35 U.S.C. § 102 and 35 U.S.C. § 103.

Claims 1-3, 5-9, 10-12, 14-18, 19-21, 23-27, 28-30, 32-36 and 58 are rejected under 35 U.S.C. §102(b) as being anticipated by or in the alternative, under 35 U.S.C. §103(a) as obvious over Buncke (U. S. Patent No. 5,931,855). Applicants submit that the Buncke reference does not anticipate or render obvious the presently claimed invention.

As stated and recognized by the Office,

> "Buncke reference fails to disclose the barb cut angle ranging from about 140 degrees to about 175 degrees, however, what is abundantly clear from Figure 15 of Buncke drawings is that the cutting blade has a sharp cutting edge, a base and an angle (see Figure below paragraph 5) whereby said angle of the cutting blade creates the barb cut angle on the suture . . . . Here it is noted that it has been held that things clearly shown in reference patent drawing qualify as prior art features, even though unexplained by the specification. In re Mraz, 173 USPQ 25 (CCPA 1972)."

Applicants vigorously disagree. The Office's citing of *In re Mraz* is not relevant in the present situation because Figure 15 of Buncke is not a greatly enlarged section of a smaller drawing. Figure 15 from Buncke is shown below:



Clearly there is no enlarged area of Figure 15 that is available to one skilled in the art. Yes, the Office attempted to provide an enlarged figure and subjected applicants to this artistic rendition in the Office Action of September 4, 2007, but the drawing by the examiner is not sufficient to meet the requirements set forth by the *Mraz* court. **Clearly, the enlarged figures have to be part of the cited Buncke reference and not drawn by the examiner**. Thus, the Office's attempt to show an enlarged sectional view does not meet the requirements set forth by the *Mraz* Court.

Further, the Office cannot ignore guidance set forth in section 2125 of the MPEP which states that:

> "When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. See *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000) (The disclosure gave no indication that the drawings were drawn to scale. "[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.")."

As stated above, the Buncke reference is completely devoid of any description relating to a discussion regarding the angles of the projected barbs, and thus, the drawings alone cannot be relied on because the drawings are devoid of specific information on sizes.

Importantly, the present invention as recited in claim 1 describes barbs having a barb cut angle Θ ranging from about 140 degrees to about 175 degrees. The claimed invention further includes barbs having a cut depth (D) formed by slicing into the suture diameter (SD) of the elongated body thereby providing barbs that have a cut length (L). This can be shown in Figure 7A, recreated from the present application, as enlarged areas of the sutures.

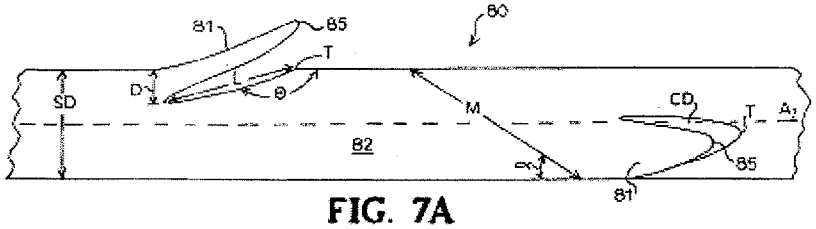


FIG. 7A

It should be recognized by the Office that knowledge relating to the value of "D," and "L" is essential and very important to clearly define the cut angle as discussed below in paragraph [0140] recreated below:

Barb cut angle Θ was measured from the surface of the cut to the outer surface of barbed suture **80**. Barb cut depth D was measured along a perpendicular from the outer surface of barbed suture **80** toward longitudinal axis A of barbed suture **80**. The measurements enabled cut length L to be calculated using the following formula.

$$L=D/\{\mathrm{Sin}(180-\Theta)\}$$

Thus, these values are important in determining the optimal range of cut angles for the present invention. Notably, there is no such disclosure, teaching or suggestion in the Buncke reference regarding the cut length of the barb (L) or the cut angle and the Office's speculation regarding Buncke is not sufficient to defeat the novelty of the present invention or establish a *prima facie* case of obviousness.

According to the Office, applicants' independent claims 10, 19 and 28 and all claims depending therefrom are obvious in light of Buncke. It should be recognized by the Office that each of these claims expressly recite the need for knowing the suture diameter "SD." Specifically, the presently claimed invention recited in independent claims 10, 19 and 28 include a barbed suture for connecting human or animal tissue, comprising

> (a) an elongated body having a first end, a second end and a diameter; and
> (b) a plurality of barbs projectable beyond the diameter of the body and returnable within the diameter of the body, each barb projecting from the body, each barb facing in a direction and being adapted for resisting movement of the suture, when in tissue, in an opposite direction from the direction in which the barb faces, wherein the barbs have a configuration comprising at least one of the following:
>
> > (i) a barb cut depth where the **ratio of the barb cut depth to the suture diameter ranges from about 0.05 to about 0.6** (claim 10),
> > (ii) a barb cut length where the **ratio of the barb cut length to the suture diameter ranges from about 0.2 to about 2** (claim 19), or
> > (iii) a barb cut distance where the **ratio of the barb cut distance to the suture diameter ranges from about 0.1 to about 6** (claim 28).

Thus, claim 10 of the presently claimed invention recites a **ratio (D:SD)** of the barb cut depth (D) to the **suture diameter** (SD) wherein the ratio is from about 0.05 to about 0.6; claim 19 recites a **ratio (L:SD)** of the barb cut length (L) to the **suture diameter** (SD) wherein the ratio is from about 0.2 to about 2: and claim 28 recites a barb suture comprising a barb cut distance **(P:SD) with ratio** of the barb cut distance (P) to the **suture diameter** (SD) that ranges from about 0.1 to about 6. The specific ratios recited in the claims all include the **suture diameter SD** so clearly **this is an important numerical value.**

The Buncke reference does not provide a clear definitive statement regarding the suture diameter (SD) and one skilled in the art viewing the drawings of Buncke, including Figures 15, 17 and 18 as set forth below, would recognize that there is a great deal of ambiguity regarding the dimensions the Buncke suture diameter. Is the diameter of the suture, the larger uncut body, or is suture diameter determined after the barb is cut? This value is important and a reference such as Buncke that gives no clear and unambiguous information regarding the suture diameter cannot possibly render the present invention as obvious.

Fig. 15

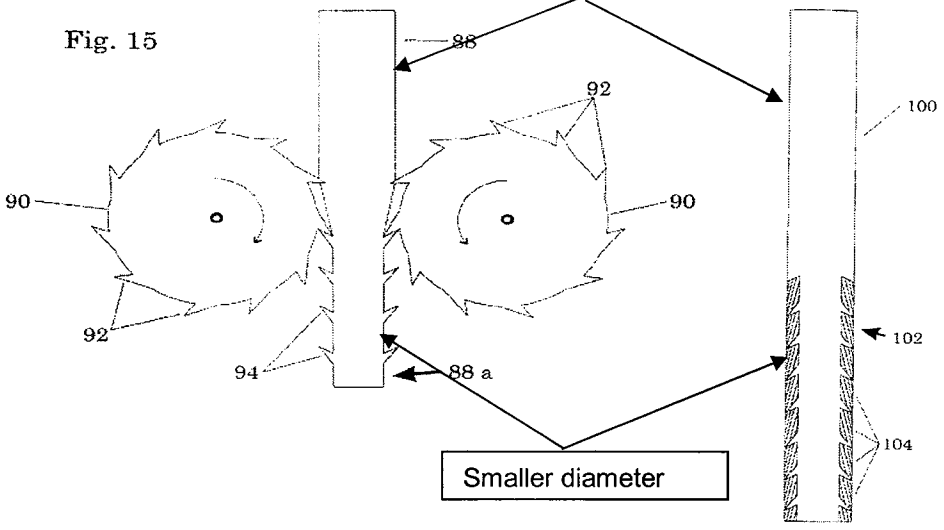
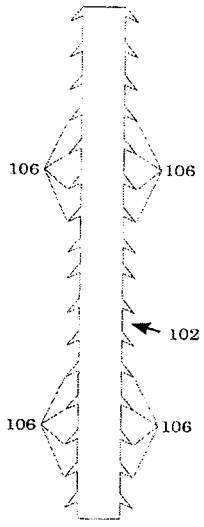


Fig. 17

Fig. 18



Further, Buncke does not in any way disclose the use of such "Suture Diameter" to calculate a ratio, as recited in applicants' claims 10, 19 or 28, and the Office has not shown any disclosure, teaching or suggestion of such mathematical calculations to show that ratios were even considered by Buncke. To determine a ratio, there has to be a mathematical manipulation of data wherein a numerator is divided by a denominator. Thus, to arrive at applicants' claimed invention, one skilled in the art would have to correctly guess as to the numerator and denominator, however, without any guidance from Buncke because Buncke never even considers a ratio.

The Office mistakenly believes that the three ranges described in the Buncke reference, which includes thousands of possibilities, provides sufficient evidence to render the presently claimed compounds as *prima facie* obvious. Applicants and the Federal Circuit disagree. Notably the Federal Circuit addressed this very issue in June 2007, after the *KSR* decision, and determined that such a broad genus does not provide sufficient guidance for the ratios of the pending claims. Specifically, the Court in *Takeda Chemical Industries Ltd. v. Alphapharm Ltd.*, 83 USPQ2d 1169 (Fed. Cir 2007) determined that when the cited prior art disclosed thousands of possibilities and nothing in the prior art suggests to one skilled in the art that certain aspects were of any value, then the prior art reference does not defeat the patentability of a limited number of possibilities among the thousands of possibilities. The Court in *Takeda* further stated that when there was nothing in the prior art that would have indicated that any of the thousands of possibilities were important then there was nothing in the prior art patent that would guide one skilled in the art to narrow the possibilities to a specific group (or in the present invention "range of ratio"). (Applicants are well aware that the *Takeda* decision involved a generic molecular structure with thousand of possible structures, but the ruling is not limited to organic molecules). Because the prior art reference provides a broad selection of possibilities, but provides no guidance regarding which of the many possibilities is important for that specific purpose, then it would not fall into the situation contemplated by the *KSR* Court as an "obvious to try" invention. Clearly, there is nothing in the Buncke reference that teaches the presently claimed ratios and the Office cannot conjure this up or speculate by relying on something that is not disclosed. The Court's decision in *In re Spormann,* 150 USPQ 449 (CCPA 1966), bears directly on point:

> "Obviousness cannot be predicated on what is unknown"

In light of the above discussion, the Office has failed to establish a *prima facie* case of obviousness and applicants request the withdrawal of the rejections of claims 1-3, 5-12, 14-21, 23-30, 32-36 and 58 under both 35 U.S.C. §102(b) and §103(a).

Claims 4, 13, 22 and 31 were rejected under 35 U.S.C. §103(a) as obvious over Buncke (U. S. Patent No. 5,931,855) and further in view of Buncke (U. S. Patent No. 5,931,855). This combination cannot be correct and applicants suspect that the Office instead meant to include Leung, et al. (U.S. Patent No. 6,599,310). However, as stated in the previous response, the proposed combination of Buncke and Leung, et al is not a proper combination of references because under 35 USC §103(c), subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title shall not preclude patentability under this section [section 103 obviousness rejections] where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

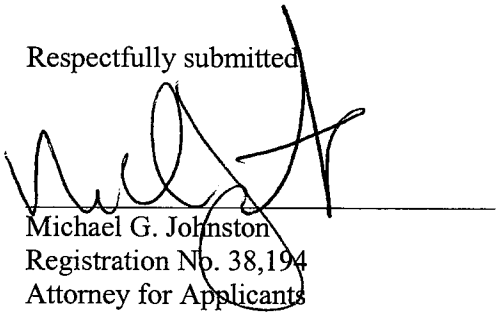
Accordingly, the Office is respectfully requested to remove the obviousness rejection based on Buncke in view of Leung et al.

Claims 115-140 were rejected under 35 U.S.C. §103(a) as obvious over Buncke (U. S. Patent No. 5,931,855) and further in view of Ruff, et al. (U.S. Patent No. 5,342,376). Applicants insist that Buncke does not disclose, teach or suggest the presently claimed invention and introducing the teachings of Ruff does not cure the shortcomings of Buncke. Again, as stated numerous times, the Buncke reference does not disclose all elements of the presently claimed invention, provides no motivation to modify the Buncke sutures and provides no direction for such modification. As such, the proposed combination by the Office does not meet the standards of establishing a *prima facie* case of obviousness and applicants request the withdrawal of this rejection under 35 U.S.C. §103(a).

As the Examiner's rejections have been shown to be in clear error and lack essential elements of a *prima facie* anticipation rejection or a *prima facie* obviousness rejection, it is requested that these claims be allowed to issue.

Respectfully submitted,

Date: 3-4-08

By: 

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